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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,946	06/11/2007	Jens Egebjerg Nielsen	P69516US1	2115

136 7590 03/09/2010

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EXAMINER	
WILSON, LARRY ROSS	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
03/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,946	NIELSEN ET AL.	
	Examiner	Art Unit	
	LARRY R. WILSON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14-28, and 30-31 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,755,173 to April A. Konopka et al. (Konopka).

In regards to claim 1, Konopka discloses an infusion device (Fig. 1)..., said infusion device comprising a base element (Fig. 11, #440), a septum housing (Fig. 11, #442), a septum pierceable by a needle (Fig. 11, #450), said base element including a fluid path (Fig. 11, #444, 446 – together form a path guiding fluid into the body of the patient) that guides fluid from a fluid inlet (Fig. 11, annular opening in #442), to a fluid outlet (Fig. 11, approximately top portion of #414 – shows radial flanges at bottom of the fluid transfer volume 50 forming the outlet communicating with the cannula) communicating with a cannula (Fig. 11, #414), said fluid path having a fluid transfer volume (Fig. 11, #444) such that walls of said fluid transfer volume are in contact with the fluid and such that said walls of the fluid transfer volume are at least partially formed by walls of a recess in the base element (Fig. 11, #440 – has notches forming recess for septum and forms walls of fluid transfer volume 444), said septum being accommodated in and fixed inside said septum housing (Fig. 11, #442, 454 – 442 surrounds septum

creating a housing), and said septum housing being accommodated in and fixed inside said recess of said base element (col. 13, lines 19-20).

In regards to claims 15-28, and 30-31, Konopka discloses the infusion device according to claim 14, and further teaches:

Claim 15: said septum housing has an opening through which said fluid in the fluid transfer volume is in contact with said septum (Fig. 11, #444 – fluid would necessarily touch the inner surface of the septum);

Claim 16: said septum housing is a tubular element accommodating said septum (Fig. 10, #442), at least one end of said tubular element forming a substantially partial enclosure over one surface of said septum (Fig. 11, #442 – shows opening to allow needle insertion through septum);

Claim 17: said septum housing includes an integrally formed cannula bushing (lower surface of Fig. 11, #68 and upper surface of support ledge #48 by compression force inherently forms a bushing – similar notched structure supports septum 450 and forms cannula bushing);

Claim 18: one surface of said septum is substantially exposed (Fig. 11, #450 – surface facing 444);

Claim 19: said septum housing is fixed to said base element by welding (col. 9, lines 43-46);

Claim 20: said septum housing is fixed to said base element by welding is ultrasonic welding (col. 9, lines 43-46);

Claim 21: said septum housing is fixed to said base element by a snap-lock (col. 9, lines 43-46);

Claim 22: said septum housing is fluid-sealed by ultrasonic welding to said base element (col. 9, lines 43-46 –since the cap 56 provides compressive force to the septum that when this is sealed using welding as disclosed the housing would also be fluid sealed);

Claim 23: said septum housing is fluid-sealed by a gasket arranged between said septum housing and an inner section of said recess (Fig. 7A, #152 – vulcanized silicone forms seal and gasket between hub 48 and cap 56);

Claim 24: said septum is fixed inside said septum housing by friction (col. 8, lines 32-34 –a component is sized larger than the holder to retain it inherently forms a friction fit);

Claim 25 & 26: said septum is fixed inside said septum housing by welding; wherein said septum is fixed inside said septum housing by welding is ultrasonic welding (col. 9, lines 30-32, 43-44 – "septum layers 52, 54 may be sealably bonded to upper portion of the hub 48 so as to cover or seal the chamber 50");

Claim 27: said septum is radially compressed and is configured to assist in the fixing and fluid-sealing of said septum housing to said base element (col. 8, lines 18-20 – which ensures a tight seal as expressed in col. 7, line 68-col. 8, lines 4);

Claim 28: a fluid-tight seal between said septum and said septum housing is provided by (i) a resilient material (col. 8, lines 38-48) and selected dimensions of said septum and

said septum housing (col. 8, lines 32-34), and (ii) said septum being substantially mainly radially compressed in said septum housing (col. 8, lines 18-20);

Claim 30: said septum housing is provided as a single piece (Fig. 12, #442);

Claim 31: said recess forms a cavity accommodating said septum housing and said septum (col. 8, lines 32-34 – there would be cavity to hold the septum and housing if the septum is slightly larger than the opening in order to impart compressive radial forces).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Konopka.

In regards to claim 29, Konopka teaches the infusion device according to claim 14, but does not teach wherein said septum is premountable in said septum housing. Konopka teaches "the central hub 248 is mounted in a domed base 246" (col. 10, lines 56-57) and "Two septum layers 252, 254 are mounted in the central hub 248…" (col. 10, lines 60-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have rearranged the mounting order of the septum to the central hub before bonding the central hub to the base as taught by Konokpa (col. 10, lines 56-57, 60-62) to allow for the sterilization of the interior surfaces of both the central hub and base before

bonding together so as to prevent infection when used to infuse fluids to a patient. See MPEP 2144.04 – Rearrangement of parts.

Response to Amendment

5. The amendment to claim 14 in the response filed on 14 December 2009 is acknowledged.

Response to Arguments

6. Applicant's arguments with respect to claims 14-31 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's are moot because applicant amended the claims to recite features of another embodiment of the applicant's disclosed invention, necessitating a new ground of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LARRY R WILSON/
Examiner, Art Unit 3767

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767